K113095

MAR - 2 2012

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. **Submitter Contact Information:**

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   Chubei City, 302, Taiwan
   Contact:
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2. **Name of Device:**

   E-Care Infrared Ear Thermometer, models: LCT-300 and LCT-600

3. **Predicate Device:**

   Braun Thermoscan Infrared Ear Thermometer model: IRT3520 (K983295)

4. **Device Description:**

   4.1 General description:

   The E-Care Infrared Ear Thermometer, models LCT-300 and LCT-600 is a hand-held, battery-powered electronic thermometer which uses an infrared sensor (thermopile) to detect body temperature from auditory canal. Its operation is based on measuring infrared radiation from the tympanic membrane and the surrounding tissue. The signal of sensor is calculated and display by an ASIC controlled circuit. This device consists of a thermopile for the measuring sensor, an ASIC controlled circuit for calculating the electrical signal and an LCD to display the measured temperature.

   By inserting the probe of this infrared ear thermometer into the outer canal, press the measurement button to start measurement. The electronic circuits amplify and calculate the signal of sensor, then display the temperature on LCD display. The total operation takes a few seconds.

   4.2 Difference between LCT-300 and LCT-600:

   LCT-300 and LCT-600 use the same electronic components and software (firmware). Basically, their operation is the same, but there are some differences between them:

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1. Different shape (outlooking).
2. LCT-300 does not use probe cover and LCT-600 uses probe cover. During the calibration process in factory, LCT-300 does not have a probe cover on it and LCT-600 does. So LCT-300 (without using probe cover) and LCT-600 (with probe cover) can have the same measurement accuracy after calibration. In their individual user manual, there is different description of usage methods to ensure correct measurement.

5. Intend for Use:

The E-Care Infrared Ear Thermometer, models: LCT-300 and LCT-600,
is an electronic clinical thermometer using an infrared sensor to detect body temperature from auditory canal for people of all ages at the home.

6. Comparison to Predicate Device:

Both the subject devices (LCT-300 and LCT-600) and predicate device (Braun Thermoscan Infrared Ear Thermometer model: IRT3520 (K983295)) use the same fundamental technology and have the same intended use. The following is the comparison table between the subject devices (LCT-300 and LCT-600) and predicate device (Braun IRT3520):

Features	Predicate Device (IRT3520)	Subject Device (LCT-300)	Subject Device (LCT-600)
510 (k) #	K983295	K	K
*Displayed Temperature Range	34~42.2℃ (93.2~108°F)	0~50℃ (32~122°F)	0~50℃ (32~122°F)
Operating Ambient Temperature Range	10-40℃ (50-104°F)	10-40℃ (50-104°F)	10-40℃ (50-104°F)
Display Resolution	0.1℃ or °F	0.1℃ or °F	0.1℃ or °F
Sensor Type	Thermopile	Thermopile	Thermopile
*Accuracy	±0.2℃	±0.2℃ (0.4°F) : 36~39℃ (96.8~102.2°F) ±0.3℃(0.5°F): 34~36 & 39~43 ℃ (93.2~96.8 &	±0.2℃ (0.4°F) : 36~39℃ (96.8~102.2°F) ±0.3℃(0.5°F): 34~36 & 39~43 ℃ (93.2~96.8 &

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		102.2~109.4°F)	102.2~109.4°F)
*Memory	8	10	10
*Battery	2 X CR2032	1 X CR2032	1 X CR2032
*Probe Cover	With	Without	With

※ The subject device and predicate device are different for these features with "*".

The difference in these features does not affect the intend use and alter the fundamental scientific technology of these devices. Moreover these verification and validation test contained in this submission demonstrate the difference in subject devices could maintain the same safety and effectiveness as predicate device. Thus, the E-Care Infrared Ear Thermometer, model LCT-300 and LCT-600 is substantially equivalent to the Braun Thermoscan Infrared Ear Thermometer model: IRT3520 (K983295).

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as following:**
   Compliance to applicable voluntary standards includes ASTM E1965 as well as IEC 60601-1 and IEC 60601-1-2.
8. **Discussion of Clinical Tests Performed for Determination of Substantial Equivalence:**
   A clinical test report was conducted accord ASTM E1965 . This report was carried out in such a way that compared the accuracy performance between the E-Care Infrared Ear Thermometer, models LCT-300 and LCT-600, and the predicate device. The results of this clinical test reports positively support the claim of Substantially Equivalence for LCT-300 and LCT-600 against the chosen 510k predicate device.

9. **Conclusions:**
   The E-Care Infrared Ear Thermometer, Models LCT-300 and LCT-600 have the same intended use and similar characteristics as the cleared device Braun Thermoscan infrared ear thermometer model: IRT3520 (K983295). Moreover, clinical testing contained in this submission demonstrates that any difference in their technological characteristics do not raise any question of safety or effectiveness. Thus, the E-Care Infrared Ear Thermometer, Models LCT-300 and LCT-600 are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kun-Yuan Ko
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TAIWAN 30252

MAR - 2 2012

Re: K113095
Trade/Device Name: E-Care Infrared Ear Thermometers
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 6, 2012
Received: February 13, 2012

Dear Mr. Ko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use:

510(k) Number (if known):
Device Name: E-Care Infrared Ear Thermometers
Models: LCT-300 & LCT-600

- Indications for use:

The E-Care Infrared Ear Thermometer, models: LCT-300 and LCT-600,
is an electronic clinical thermometer using an infrared sensor to detect body temperature from auditory canal for people of all ages in the home.

Prescription use _____ and / or Over-The- Counter Use _V__
(21CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 3/1/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113095